

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison between effect of 5% and 7% saline on bronchiolitis treatment in infants

Protocol summary

Summary

This study is designed to compare the effects of hypertonic saline 5 and 7% in the treatment of bronchiolitis in infants aged 2 months to 2 years. The study population will be 90 children aged 2 to 24 months with viral bronchiolitis admitted to Ardabil Buali hospital. Patients will be entered in this study with block randomization method of sampling and they will be divided into three groups of 30 people. This will be a double blind study namely both the subjects participating and the researchers will be unaware of medication type. Inclusion criteria are first or second episode of respiratory distress with wheezing and diagnosis of viral bronchiolitis based on the standard definition of bronchiolitis. Exclusion criteria are history of previous wheezing attacks more than 2 times, heart and lung disease, immunodeficiency, Down syndrome, metabolic diseases, use of mechanical ventilation, positive family history of asthma, and Patients who are critically ill. The first group will be treated with 0.15 mg/kg adrenaline along with hypertonic saline 5%, The second group will be treated with 0.15 mg/kg adrenaline along with hypertonic saline 7%, and the third group as the control group will be treated with the standard treatment, namely, 0.15 mg/kg adrenaline along with normal saline 0.9%. For all patients in the three groups, clinical symptoms (cough, wheezing, respiratory rate, heart rate, fever, crackles, oxygen saturation) and length of hospital stays will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090717843N5**

Registration date: **2015-12-09, 1394/09/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-09, 1394/09/18

Registrant information

Name

Adel Ahadi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1773 1210

Email address

a.ahadi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ardabil University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between effect of 5% and 7% saline on bronchiolitis treatment in infants

Public title

The comparison between effect of 5% and 7% saline on bronchiolitis treatment in infants

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: first or second episode of respiratory distress; wheezing; diagnosis of viral bronchiolitis based on the standard definition of bronchiolitis. Exclusion criteria: History of previous wheezing attacks more than 2 times; heart and lung disease; immunodeficiency; Down syndrome; metabolic diseases; use of mechanical ventilation; positive family history of asthma; and Patients who are critically ill.

Age
From **2 months** old to **2 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Research samples will be divided into three equal groups using block randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, daneshgah Street, Ardabil.

City

Ardabil

Postal code

Approval date

2015-08-08, 1394/05/17

Ethics committee reference number

IR.ARUMS.REC.1394.19

Health conditions studied

1

Description of health condition studied

Acute bronchiolitis

ICD-10 code

J21

ICD-10 code description

Acute bronchiolitis

Primary outcomes

1

Description

Oxygen Saturation

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

Using pulse oximetry

2

Description

Respiratory rate

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

counting the number of breaths for one minute

3

Description

Heart rate

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

counting the number of heartbeats for one minute

4

Description

Fever

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

Using a thermometer

5

Description

Crackles

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

Examination

6

Description

cough duration

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

Patient observation and counting days till fully recover from cough

7

Description

Wheezing duration

Timepoint

Every 6 hours for 24 hours after admission, and then once a day until discharge

Method of measurement

Physical examination

8

Description

duration of hospital stay

Timepoint

Since the start of admission until discharge

Method of measurement

Counting the days of hospitalization

Secondary outcomes

empty

Intervention groups

1

Description

First group: 10 mL of 5% hypertonic saline with 0.15 mg/kg adrenaline

Category

Treatment - Drugs

2

Description

Second group: 10 mL of 7% hypertonic saline with 0.15 mg/kg adrenaline

Category

Treatment - Drugs

3

Description

Third group: standard treatment: 10 mL of 0.9% normal saline with 0.15 mg/kg adrenaline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital

Full name of responsible person

Dr Adel Ahadi

Street address

Bu-Ali Hospital, Saheli street, Ardabil

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ardabil University of Medical Sciences

Full name of responsible person

Dr Shahram Habibzadeh

Street address

Ardabil University of Medical Science, Daneshgah Street, Ardabil

City

Ardabil

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Fatemeh Amani

Position

Medical Resident

Other areas of specialty/work

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Fax

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Adel Ahadi

Position

Pediatrics Specialist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Fatemeh Amani

Position

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Other areas of specialty/work

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eng.m.amani@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty